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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,772	02/12/2004	Atsuo F. Fukunaga	10437-69	2944

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EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/777,772

Applicant(s)

FUKUNAGA ET AL.

Examiner

Darwin P. Erezio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,8,9,11,12,15-18,20-22 and 25-32 is/are pending in the application.
- 4a) Of the above claim(s) 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,8,9,11,12,15-18,20-22,25-29,31 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claim 30 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/27/06.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1, 2, 15, 17 and 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,463,755 to Suzuki.**

(claim 1) Suzuki still discloses a multilumen, unilimb breathing circuit comprising first **2** and second **5** conduits, each of the conduits having a proximal and a distal end (see Fig. 1), wherein the proximal end of the first conduit can be operatively connected to an inlet for respiratory gases via port **17**, and the second conduit can be can be operatively connected to an outlet for respiratory gases via port **6**, wherein the first and second conduits comprise pleated or corrugated tubing (col. 5, lines 26-39), the conduits being connected at their distal ends to a common distal fitting , wherein the first and second conduits meet the flow requirements for spontaneous or assisted ventilation, and wherein the distal fitting can be detachably connected directly to a patient interface consisting of a mask (see col. 1, lines 20-22; col. 14, lines 35-36).

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(claim 2) The first and second conduits have a common proximal fitting, as seen in Fig. 6.

(claim 15) Fig. 1 shows the first and second conduit comprising pleats or corrugation having wavelengths that are proportional in size.

(claim 17) The first conduit is contained within the second conduit, see Fig. 1.

(claims 26-28) Suzuki teaches an anesthesia system (col. 1, line 14).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claims 4, 5, 8, 9, 11, 12, 16, 18, 20 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki in view of WO 85/05277 to Clawson et al.**

(claim 4) Suzuki teaches the first and second conduits formed from corrugated tubing (col. 5, lines 26-39) but is silent with regards to the conduits being able to retain its shape after axial extension or contraction, wherein the first conduit will expand or

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contract in length with corresponding axial expansion or contraction of the second conduit.

However, Clawson teaches a multilumen, unilimb breathing circuit comprising a first **108** and second **110** conduits; wherein the conduits are formed from pleated or corrugated tubing that is capable of retaining its shape (page 5, first complete paragraph); and wherein the first and second conduits have common proximal and distal ends (Fig. 4) so that when the second conduit is expanded or contracted, the first conduit will simultaneously expand and contract along with the second conduit.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Suzuki to use the corrugated tubing of Clawson because using Clawson's corrugated tubing eliminates the need of stocking and shipping breathing circuits of different lengths (page 3, second paragraph). Clawson's corrugated tubing can be increased or decreased to a desired length without cutting or substitution.

(claim 5) Suzuki teaches the first and second conduits having a common proximal fitting (Fig. 6) and a common distal fitting (Fig. 4). Therefore, the modified breathing circuit of Suzuki/Clawson will also have a first and second conduits sharing a common proximal fitting and a common distal fitting.

(claims 8 and 9) It would be inherent that axially extending or contracting the modified breathing circuit of Suzuki/Clawson would also adjust the volume within the first or second conduit; i.e., a shorter tubing would have less volume than a longer tubing.

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(claims 11 and 12) Clawson teaches the first or inner conduit made of the corrugated tubing that can retain its shape. Therefore, the modified first conduit of Suzuki/Clawson could have a longer length than the second conduit when the first conduit is not constrained by the mutual fittings since the first conduit could be extended to a retained length and the second conduit could be contracted to a shorter, retained length.

(claim 16) The combination of Suzuki/Clawson discloses the claimed invention except for the conduits having a resistance to flow of less than about 6 cm H₂O at flow rates of up to about 60 l/min. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the recited ranges, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Furthermore, it would be obvious to arrive at the recited ranges since Suzuki teaches a device used for providing breathable gases to a patient.

(claims 18 and 20) Suzuki teaches the first conduit contained within the second conduit and being coaxial therewith (Fig. 1).

(claim 29) Suzuki teaches an anesthesia system (col. 1, line 14).

7. Claims 21, 25 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki in view of US 5,778,872 to Fukunaga et al.

Suzuki teaches all the limitations of the claims but is silent with regards to the proximal fitting having at least two lumens with filters. However, Fukunaga teaches a

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similar unilimb breathing circuit having a proximal fitting with two lumens having filters (158,168). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the proximal fitting of Suzuki to include the two filters taught by Fukunaga because it prevent other components connected proximally of the filter from contamination by patient expiratory gases.

Suzuki also teaches the circuit for use in an anesthesia system (col. 1, line 14).

8. Claims 22 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki in view of Clawson et al. and in further view of US 5,778,872 to Fukunaga et al.

The above combination of Suzuki/Clawson teaches all the limitations of the claims but is silent with regards to the proximal fitting having at least two lumens with filters. However, Fukunaga teaches a similar unilimb breathing circuit having a proximal fitting with two lumens having filters (158,168). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the proximal fitting of Suzuki/Clawson to include the two filters taught by Fukunaga because it prevent other components connected proximally of the filter from contamination by patient expiratory gases.

Suzuki also teaches the circuit for use in an anesthesia system (col. 1, line 14).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. At least claims 4 and 5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 5 of copending Application No. 10/942,230. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structural limitations recited in the instant application are also recited in the copending application.

For example, claim 4 of the instant application and claim 1 of the copending application both recite a multi-lumen, unilimb breathing circuit comprising a first and second conduits, each having a proximal and distal ends, wherein the distal end is attached to a patient interface, and wherein the axial extension or contraction of the distal end of the second conduit causes a corresponding axial extension or contraction of the distal end of the first conduit, wherein the second conduit is capable of retaining a second conformation, and wherein the first conduit will expand or contract along with the second conduit. The difference between the claims lies with the terminology used to recite each structure and how they relate to each other. However, this subtle difference

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in claim terminology would be obvious to one of ordinary skill in the art because the cited structures of either claims are similar.

With regards to claim 5, see claim 5 of the copending application

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

11. Applicant's arguments filed 11/27/06 have been fully considered but they are not persuasive.

The applicant argued that Suzuki fails to teach a pleated tubing because the tubing of Suzuki is not capable of retaining its expanded or contracted length or shape after axial expansion and contraction. However, it is noted that the features upon which the applicant relies (i.e., retaining shape) are not recited in the rejected claim(s) under 35 USC 102. Furthermore, the broadest reasonable interpretation for the limitation "pleated" is "folded" (www.m-w.com). Therefore, the corrugated or folded tubing of Suzuki is viewed as pleated tubing.

12. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA

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1971). In this case, Clawson's corrugated tubing eliminates the need of stocking and shipping breathing circuits of different lengths (page 3, second paragraph).

In response to applicant's arguments regarding the unexpected result or commercial success of the instant invention, the applicant is reminded that evidence for secondary arguments must be provided in an affidavit or declaration format. The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Furthermore, the argument regarding commercial success and unexpected result of the invention does not overcome the rejection over Suzuki in view of Clawson because the teaching reference, Clawson, discloses that having corrugated tubing that can retain its shape eliminates the need of stocking and shipping breathing circuits of different lengths.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Darwin P. Erezzo
Examiner
Art Unit 3731


de


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
